Current Trends in Implantable Hearing Aids

Marshall Chasin, M.Sc., Reg. CASPLO, Aud(C), FAAA
Audiologist and Coordinator of Research, Canadian Hearing Society, Toronto, Canada

When the research is examined historically, there appear to be three rationales for developing and fitting implantable hearing aids (IHA). These include improved (a) sound reception, (b) cosmetics, and (c) fitting of patients who could not derive optimal benefit from conventional amplification. With the introduction of modern completely-in-the-canal (CIC) hearing aids, the cosmetic concern is no longer a major motivation. (Johnson and Danhauer, 1997). Dumon et al (1995) clearly stated the ultimate goal of IHA research is the creation of a ". . . totally implantable middle ear implant (MEI), for severe and average [moderate] sensorineural deafness." Until the technology is available to provide a totally IHA, Goode et al (1995) defined an implantable hearing aid as a class of electronic devices that are "wholly or partially implanted through surgery and . . . [are] designed to ameliorate hearing loss." This definition not only covers the various middle ear implants, but also the temporal bone implants. This latter group is generally referred to as bone anchored hearing aids. Both of these types of IHAs will be discussed in great detail in this issue of *Trends*.

Like any dynamic area of research, spin-offs of this technology are already available in related areas, such as a middle ear pump system designed to release small amounts of antibiotics for chronic otitis media (Maassen et al, 1996), and as a "transparent link [to the temporal bone] in the study of tinnitus. . ." (Downing, 1996).

Goode et al (1995) and Ko et al (1995) delineated some of the parameters that an IHA should possess. As a general set of requirements these researchers suggested that IHAs should:

(1) provide sufficient gain and output for the patient's needs,
(2) not reduce residual hearing by having minimal loading or contact with middle ear structures,
(3) not limit daily activities such as swimming,
(4) not predispose the patient to recurrent ear infections,
(5) have proven long-term stability and tolerance to anatomical changes,
(6) have a demonstrated biocompatibility of the implanted materials and package,
(7) have minimal movement of the implanted parts in order to minimize wear and tear,
(8) be adjusted/programmed and removed easily with an external battery,
(9) have safety of the surgical procedure demonstrated, and
(10) allow the patient the ability to wear a conventional hearing aid if for some reason the IHA breaks or does not provide sufficient benefit.

Given the definition of IHAs, there is no reason to assume that the various devices should be restricted to only one type of hearing loss. Indeed, many of the various IHA projects that are underway around the world can be applied to sensorineural, conductive, and mixed hearing loss, despite the original intent of the researchers.

The discussion of IHAs in this manuscript is divided into two main sections; (a) bone anchored hearing aids and (b) middle ear implants (MEI). As the names suggest, a portion of a bone anchored hearing aid is surgically implanted in the temporal bone, whereas the middle ear implants are to be found partially implanted in the middle ear cavity.

BONE ANCHORED HEARING AIDS (BAHA)

The phrase, bone anchored hearing aid is used here as a generic term for any hearing aid that is coupled either magnetically or directly to the temporal bone. This phrase (i.e., BAHA™) is also the

commercial name of the device marketed by Nobel Biocare (previously Nobel Pharma), but it will be used to refer to both the BAHA™ and the Xomed, Inc., Audiant™.

A patient may be a candidate for a bone anchored hearing aid if they derive limited benefit from conventional amplification, and their hearing difficulties are primarily due to medically and surgically non-treatable ear disease, such as a non-resolving chronic otitis media. Therefore these hearing aids are primarily used for conductive or mixed hearing loss.

Understandably, various countries around the world have differing regulations and approval criteria, for the fitting of these devices. In many European countries, only the percutaneous Nobel Biocare BAHA™ is approved. In Canada, both the Nobel Biocare BAHA™ and the Xomed Audiant™ are approved, and in the United States, the Xomed Audiant™ is approved by the Food and Drug Administration (FDA) for adults and children, while the Nobel Biocare BAHA™ is approved only for adults. It is suspected that a more general approval will be obtained in the future, as more centers report their clinical results.

Bone Conduction Transmission

Bone conduction has been well studied and the basis of its behaviour can be found in most audiology texts. Briefly, Tonndorf (1966) discussed three mechanisms for a bone conducted sound reaching the cochlea: (1) High-frequency (HF) energy transmission radiated to the outer ear canal; (2) mid-frequency (MF) energy transmission as a result of inner ear structure compression, and (3) low-frequency (LF) energy transmission as a result of the inertia between the middle ear ossicles and the cochlear fluid. A model of these three sound transmission pathways (i.e., LF, MF, and HF) is shown in Figure 1.

For conductive hearing loss, bone conduction hearing aids have been found to be quite useful for a small segment of the population who cannot wear conventional air conduction hearing aids due to recurrent ear infection, or because of congenital outer ear abnormality. However, traditional bone conduction hearing aids have some limitations including: irritation caused by the oscillator being held against the mastoid process, the requirement for a headband or other mechanism to attach the hearing aid to the mastoid process, limited gain and output, and in many cases, less than an optimal frequency response. Understandably, patient discomfort and poor sound quality are common complaints. In addition, the sound delivered by a bone conduction hearing aid may not be consistent on a daily basis. The patient may position the bone conduction oscillator in a slightly different location from day to day and the force provided by the headband or eyeglass frame may decrease overtime. Such a patient could potentially derive significant benefit from a bone anchored hearing aid.

Estimated Prevalence of Candidates for BAHAs

It is difficult to establish the exact number of patients who could benefit from a bone anchored hearing aid, but the prevalence of patients who

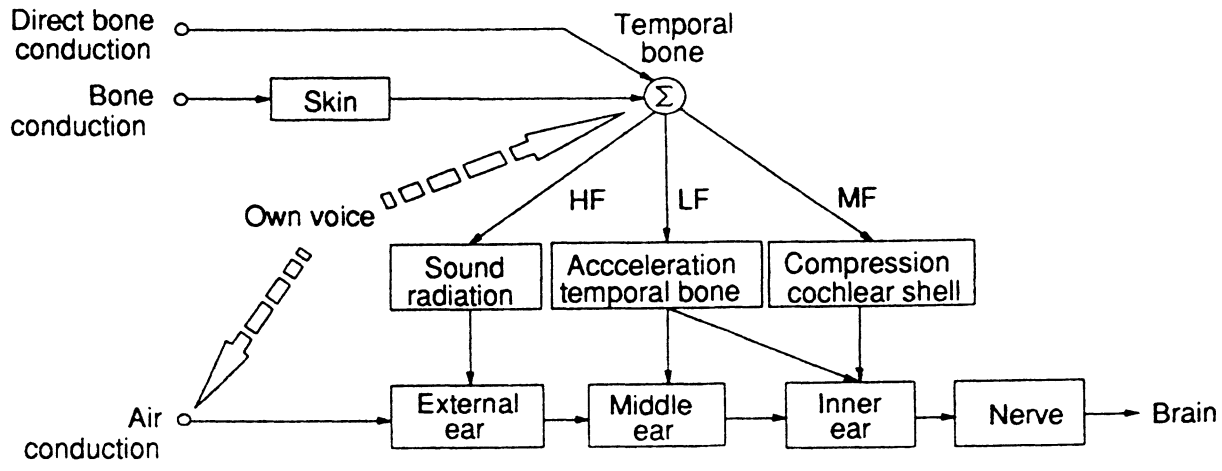

Figure 1. A simplified model of three bone conduction sound transmission pathways to the cochlea, showing both conventional bone conduction and "direct bone conduction" (described later). HF = High frequency; MF = Mid Frequency; LF = Low Frequency. Used with permission from Carlsson (1990).

could benefit from a bone anchored hearing aid is at least 2,000 to 3,000 in North America alone. This figure was calculated by examining the total number of hearing aids purchased and then determining the percentage that are recommended as bone conduction hearing aids. Figures from various hearing aid industry sources indicate that approximately 0.2 to 0.3% of all hearing aids prescribed are bone conduction hearing aids. It is true that only a small percentage of patients with hearing loss significantly effecting their ability to communicate actually acquire hearing aids. However, this is not necessarily true for those hard of hearing patients fit with bone conduction hearing aids. There undoubtedly is a much smaller percentage of patients who would normally be fit with a bone conduction hearing aid, but who choose not to obtain one. In addition, there is an unspecified number of hearing aid consumers who wear air conduction hearing aids with limited benefit that may also be candidates for a bone anchored hearing aid.

The figure of 0.2 to 0.3% can be compared with a study by Stevenson et al, (1950) that states that the incidence of malformation of the external ear was 2.41 per 10,000 births (or 0.024%) in Britain. If these data can be extrapolated to North America, this indicates that approximately 10% of the potential patients for a bone anchored hearing aid will have congenital deformities such as atresia and the other 90% will be patients who suffer from unresolvable chronic ear disease. Indeed, an informal survey of many implant programs around the world indicate that the 10% to 90% division is relatively accurate. The only exception would be for programs that specialize in children (ages 2-15 years) and clearly the vast majority of implants, would be for congenital atresias (Granstrom and Tjellstrom, 1996). Patients with some common cranio-facial syndromes such Treacher Collins and Goldenhar's Syndrome may also obtain benefit from bone anchored hearing aids. In pediatric programs, children with these two syndromes alone typically comprise at least 60% of the implant population (Powell, 1996).

Hakansson et al (1990), reviewed ten years of experience with bone anchored hearing aids in Sweden and found that 16 out of 147 patients (10.8%) had congenital malformations. In that same study, it was noted that 54% of the implant patients had previously worn bone conduction hearing aids and 34% had previously worn air conduction hearing aids only. Three percent of their implant patients had never worn a hearing aid.

Principle of Osseointegration

The study of bone anchored hearing aids was made possible because of the discovery of the process of osseointegration by Branemark and his colleagues in Sweden (Branemark, 1985). The first application of osseointegration on humans was in 1965 and was used for oral implants, as an alternative to dentures for those who had difficulty wearing them (Tjellstrom et al, 1981; Tjellstrom, 1989; Tjellstrom et al, 1989; Hakansson et al, 1990). Titanium implants for bone anchored hearing aids have been in use since 1977.

Branemark (1985) defined osseointegration as "a direct structural-functional connection between ordered living bone and the surface of a load-carrying implant." A medical grade titanium or stainless steel screw can be threaded into living bone and after a period of time (typically three months) a mechanically solid connection is formed between the implanted screw and the bone. Depending on the location and the load that must be carried, the shape and size of the screw may differ. Figure 2 shows the various components, including the titanium screw, that are typically used for bone anchored hearing aids.

Hakansson et al (1990) reported on a review of 167 patients who received implants in the 1980s. In this study, a total of 16 had had difficulties in which additional surgery was required. Of these 16 cases, only one patient had an implant that had failed to osseointegrate. Because of improved techniques and equipment, the failure to osseointegrate is less than 2% regardless of whether there was a one-stage or two-stage surgery (Tjellstrom and Granstrom, 1995). Seventy-five percent of the pa-

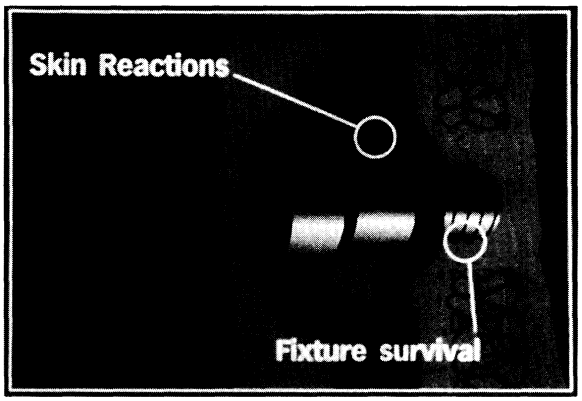

Figure 2. Various parts, including a titanium screw that are used for the attachment of bone anchored hearing aids. Photograph courtesy of Nobel Biocare.

tients in Tjellstrom's large series of over 2,000 patients never had a single episode of adverse skin reaction such as swelling or excessive redness. (Holgers et al, 1988). It is a small group of patients who are responsible for the majority of skin reactions.

Parkin (1996) examined some of the factors and materials that could affect osseointegration and concluded that among the various materials used, even though stainless steel will allow osseointegration, "textured titanium pedestals . . . achieved the best osseointegration." The titanium screw is connected laterally to a structure that either (1) protrudes through the skin (percutaneous) or (2) communicates energy across the skin (transcutaneous) by an implanted magnet being in close proximity to an external coil. Figure 3 shows these two approaches of communicating sound energy to the temporal bone.

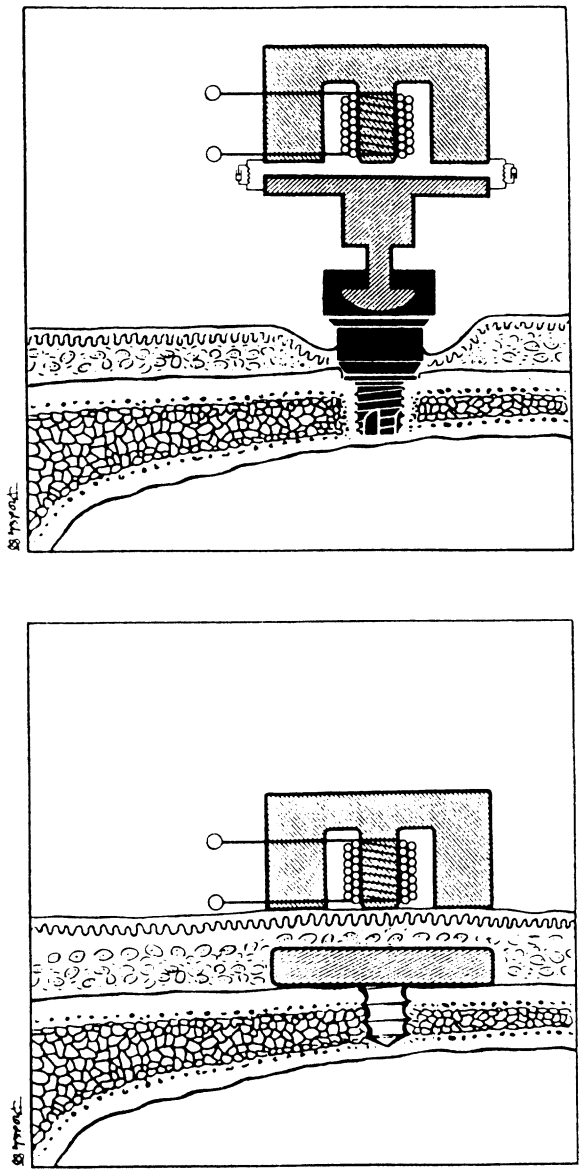

Figure 3. Two approaches (transcutaneous and percutaneous) of communicating sound energy to the temporal bone. The percutaneous approach (BAHA™) is on the top and the transcutaneous approach (Audiant™) is on the bottom. Used with permission from Carlsson (1990).

Branemark (1985), Tjellstrom (Tjellstrom, 1989; Tjellstrom et al, 1981; 1983; 1989; 1995), Hough (Hough et al, 1986a; 1986b; 1987; 1995), and Gates (Gates et al, 1989), are all well known surgeons who have pioneered the surgical techniques in order to facilitate osseointegration. Briefly, the surgery consists of the drilling of a hole into the temporal bone followed by a tapping of a threading screw into this hole. In both the transcutaneous and the percutaneous surgeries (usually performed under a local anesthetic), the skin and subcutaneous grafts from the back of the pinna are thinned out and placed over the implant site. This is done in order to provide improved magnetic attraction and to minimize skin reactions and infection. Some surgeons are no longer using a graft and are merely thinning out the skin over the implant site. In the case of the percutaneous surgery, a small hole is created in the skin graft, or thinned out area, and an external abutment is attached (with a gold screw) to the implanted titanium screw. Initially, the percutaneous operation was performed in two stages (Tjellstrom et al, 1983), but now it is typically performed in one sitting (Carlsson, 1990; DiToppa and Liepert, 1993). The one stage transcutaneous surgery has been described by Hough et al (1986b).

Transcutaneous Approach

The transcutaneous approach allows the speech signal to be transmitted across the skin via magnetic induction. An implanted magnet, whose base and screw has osseointegrated with the temporal bone, receives the signal from an external coil. This coil is adjacent to the implanted magnet, and is held in place by magnetic attraction. Dr. Hough and others have published extensively on the results of this approach. (Hough et al, 1986a; Hough et al, 1986b; Hough et al, 1987; Gates et al, 1989; Wade et al, 1989; Browning, 1990).

A major advantage of the transcutaneous approach is its improved cosmetics by having an intact layer of skin and soft tissues over the implanted

magnet. When the external hearing aid and coil is not worn, the only indication of the presence of an implanted magnet is a slight mound that can be felt under the skin posterior and superior to the top portion of the pinna, usually in the hair.

The implanted magnet is of a rare-earth type (such as neodymium iron boron) that is housed in a titanium disk. This, in turn, is covered with medical grade silicone and is attached to the temporal bone by an orthopedic screw. Hough et al (1986a) first reported on the implantation of ten patients, dating back to 1984. This approach, originally called the Temporal Bone Stimulator (TBS) (Campos, 1988) is used with most cochlear implants and has been manufactured by Xomed™ of Jacksonville, Florida under the name Audiant™. Because of some of the problems inherent in the transcutaneous approach, the manufacturer is no longer offering the Audiant™ but will offer support for repair of those units that are currently being used. Depending on the results of some technical changes, the Audiant™ may again be available in the future (Dyer et al, 1996).

The Audiant™ can be used as a body worn instrument with the coil on the end of a cord being held close to the implanted magnet. The body aid version requires two penlight AA batteries (3 volts). At-the-ear and ear-level versions are also available, utilizing one standard #675 hearing aid battery (1.4 volts), but they have slightly less output.

The at-the-ear version uses a housing that incorporates the coil, amplifier, and microphone under "one roof". An interesting feature of the at-the-ear version of the Audiant™ is that the microphone is attached to an adjustable boom that can be lengthened or shortened, so that the microphone is maintained at the typical behind-the-ear microphone location. Because the at-the-ear version might not be held completely in place by the implanted magnet, a wire bar is used to provide additional support.

The ear level aid is constructed from a modified behind-the-ear hearing aid shell (Unitron Industries, Ltd. E™-shell) with an external coil attached to a small cord connected through the audio input jack to the hearing aid. An advantage of the ear-level version over the at-the-ear version is an external coil that allows for a slightly more stable response.

Electroacoustically, the Audiant™ utilizes an input compression system with a kneepoint at approximately 60 dB SPL. Research is currently underway at the Hough Ear Institute on a linear amplifier for the Audiant™. (Dyer et al, 1996).

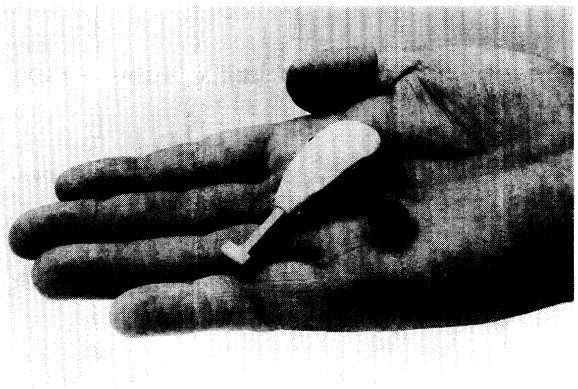

Figure 4. The transcutaneous Xomed Audiant™ at-the-ear hearing aid. Also shown is the magnet and housing that will be implanted. A body aid version and a behind-the-ear version also are available.

Only the body worn Audiant™ has a telecoil. The at-the-ear version of the Xomed Audiant™ is shown in Figure 4.

The audiometric criteria for the Audiant™ as recommended by the manufacturer are:

(1) Bone conduction pure-tone average (PTA) at 500 Hz, 1000 Hz, and 2000 Hz is not greater than 25 dB HL with no single frequency being greater than 40 dB HL in the implanted ear,
(2) Air conduction PTA not better than 40 dB HL in the implanted ear, and
(3) Word recognition score of 80% or better in the implanted ear.

In addition, for the patient deriving only limited benefit from their own amplification, the patient must be willing to return for follow-up and routine cleaning/checking of the implant site. Finally, the patient must be able to maintain good hygiene of the implant site.

Percutaneous Approach

This approach involves the use of an abutment that protrudes through the skin that is directly connected to the osseointegrated screw. The abutment contains a receptacle for the transducer of the external hearing aid that can be easily removed from a bayonette-type connector. The patient will permanently have a small abutment protruding through their skin, that is typically situated posterior and superior of the pinna and is usually covered by hair. This approach has been in use since 1977, and the results have been extensively

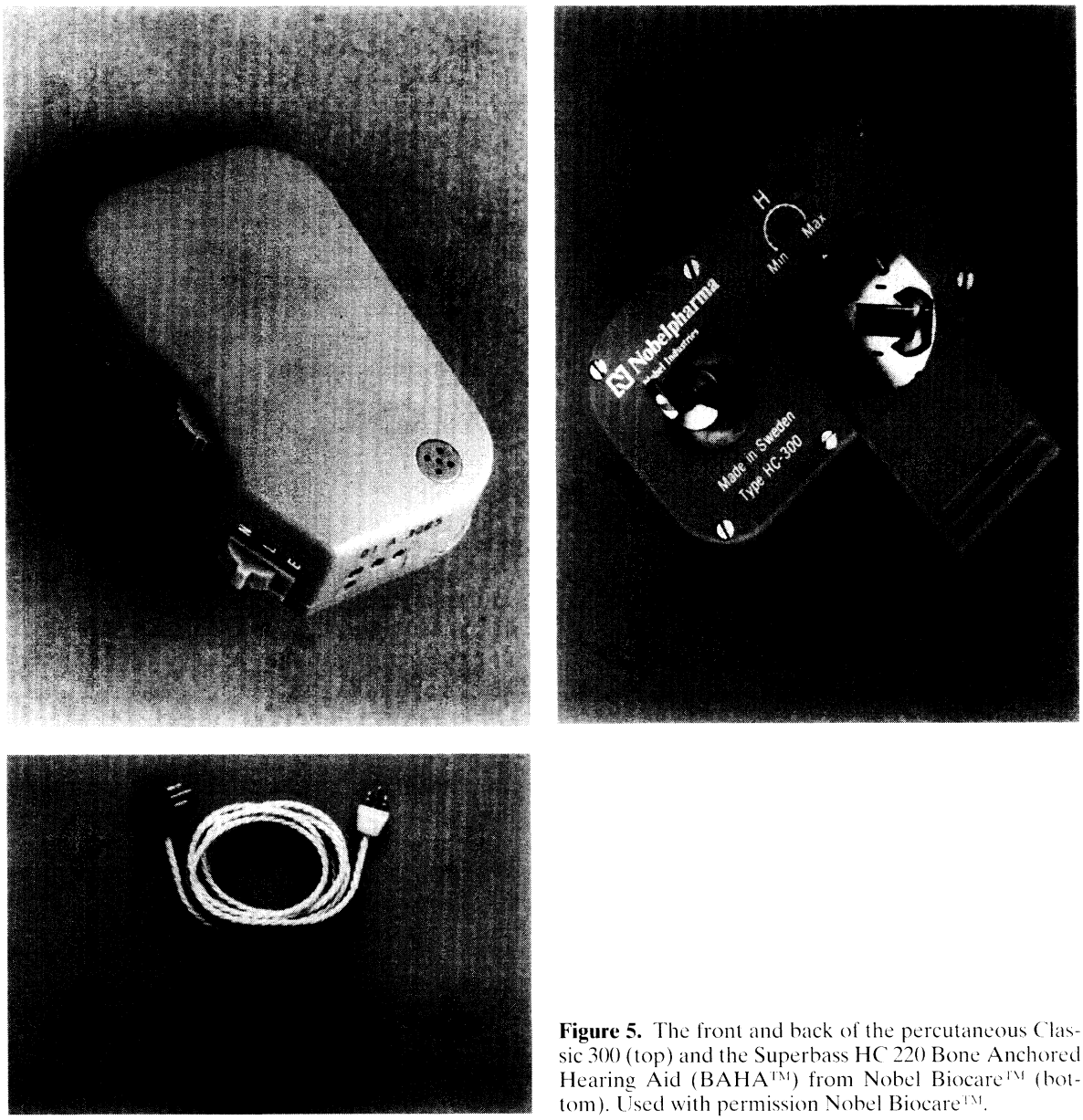

Figure 5. The front and back of the percutaneous Classic 300 (top) and the Superbass HC 220 Bone Anchored Hearing Aid (BAHA™) from Nobel Biocare™ (bottom). Used with permission Nobel Biocare™.

reported on by Tjellstrom and his colleagues (Tjellstrom, 1985).

When one initially thinks about a percutaneous implant, the negative aspect of an external abutment protruding through the skin is a significant issue. This concern is analogous to the situation where even though a behind-the-ear hearing aid is more appropriate for the patient, a canal hearing aid is desired. However, that quickly becomes secondary because of the benefits that the patient receives.

Figure 5 (top) shows the front and the back of the percutaneous Classic 300 Bone Anchored Hearing Aid (BAHA™). This hearing aid has been developed by Nobel Biocare™ in conjunction with the Department of Applied Technology at Chalmers University of Technology.

The BAHA™ has developed through several modifications over the years. These modifications include changing the transducer, including more potentiometers (overall gain, low frequency and high frequency tone controls), and miniaturization in design. The BAHA™ has direct audio input capability and a telecoil (either on a BICROS attachment or as an inductive coil that can be attached through the audio input jack). A future

version (model #360) will be even smaller than the Classic 300. In its current format, the Classic 300 contains linear signal processing. For mixed hearing losses with bone conduction thresholds between 45 dB HL and 60 dB HL, a body worn hearing aid can be coupled to a head worn transducer. This is referred to as the Superbass HC 220™, and is shown in Figure 5b. Any power body aid can be coupled to the head worn transducer as long as the output cord from the body aid has three prongs and is non-polar (e.g., Philips™ S1694). A future modification of this will be called model #380 and will be able to provide up to 10 dB greater output than the Superbass HC 220™.

The audiological selection criteria, as recommended by the manufacturer are similar to those required for the transcutaneous Audiant™, except that a bone conduction PTA is increased to 45 dB HL (c.f., 25 dB HL for the Audiant™) is acceptable (for the Classic 300 ear worn version) and 60 dB HL for the Superbass HC220 (body aid based version). In practice, this means that a patient with mixed hearing loss having a 45 dB HL bone conduction loss and no responses via air conduction, may be a candidate for such a device. When the new body worn version, model #380 becomes available, it should be useful for those with up to a 70 dB HL average bone conduction hearing loss.

Transcutaneous Versus Percutaneous Approaches

In order to compare these two approaches in terms of transduction of sound, it would be appropriate to first examine some of the characteristics of this type of transduction. Both of these devices utilize a special component referred to as a **variable reluctance transducer**. This type of transducer is a special class of a more general type- electrodynamic transducer, but has properties that make it ideal for some types of hearing aids and all audiometric bone conduction oscillators. The variable reluctance transducer is small in size and possesses a wide frequency response with a low current consumption, similar in characteristic to most conventional bone conduction hearing aids (Tjellstrom and Hakansson, 1995). The performance of such a transducer is primarily governed by the **gap distance**, **effective mass**, and the **suspension properties**. For interested readers, an excellent reference on this topic is "On Direct Bone Conduction Hearing Devices", that served as part of Peder Carlsson's Ph.D. thesis (Carlsson, 1990).

The larger the gap distance between the permanent magnet and the transducing coil, the lower the overall transducer force. Specifically the force decreases as a function of the cube of the gap distance. An external coil held away from an implanted magnet due to thick or scarred skin and subcutaneous tissues will have a larger gap with a significantly reduced transducer force. While the previous statement is generally true some data indicates a poor correlation between skin thickness and transcutaneous transduction. (Mylanus, 1994). Mylanus argues that more significant factors than the gross measurement of physical gap distance may be ". . . the thickness of different sublayers, . . ., and their damping properties." The second parameter concerns the transducer mass and its related suspension. The greater the effective mass (and the greater the compliance), the lower will be the resonant frequency of the system. A small and well controlled gap distance in conjunction with appropriate suspension characteristics, will yield a stable output and frequency response. A stable output and frequency response will allow the audiologist to predict functional benefit in an a priori manner, as well as to allow the patient to benefit fully from such a device.

As shown in Figure 3, there is a well defined (and small) gap distance in the Nobel Biocare BAHA™ system (.06 to .08 mm), but a potentially variable gap distance in the Xomed Audiant™ (typically between 4.0 mm to 8.0 mm (Mylanus, 1994)). One simply has no a priori guarantee of the degree of scarring, and to a lesser extent, the skin and subcutaneous tissue thickness, with the Xomed Audiant™. In many cases, the transcutaneous Audiant™ yields such a low magnetic output that it provides no benefit to the patient. Occasionally, the magnetic attraction is so poor that the external coil cannot be held in place by the implanted magnet.

Stated another way, with a percutaneous method of transduction one can establish a well defined transfer function between output in a test coupler and the functional gain that an individual may receive. Such a well defined transfer function cannot be as easily established for the transcutaneous method of transduction because of the uncertainties caused by the variable gap distance.

Several researchers who work with middle ear implants argue that an improvement in their method of transduction can be brought about by the use of a percutaneous method of transduction. (Suzuki et al, 1994; Maniglia et al, 1995; and Dumon et al, 1995). However, to date none of the middle

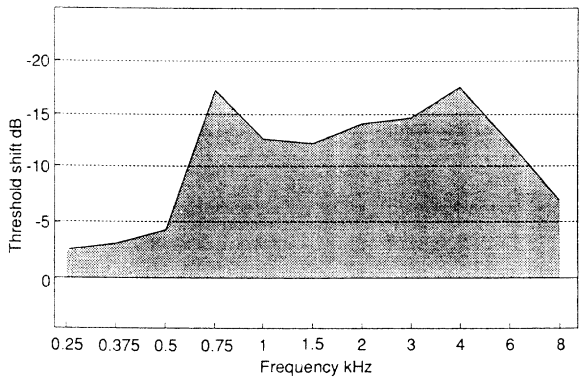

Figure 6. A 15 dB improvement in sensitivity on ten patients, when the skin was penetrated while using the same bone conductor transducer. Used with permission from Carlsson (1990).

ear programs utilize the percutaneous approach (Maniglia, 1996).

Carlsson et al (1986) demonstrated a 15 dB improvement from 750 Hz to 4,000 Hz in sensitivity on ten patients when the skin was penetrated while using the same bone conductor transducer. This is shown in Figure 6. The authors refer to this different form of transduction, as direct bone conduction, in order to distinguish it from the less sensitve bone conduction found in the transcutaneous approach. Tjellstrom and Hakansson (1995) argued that the skin penetrating feature found with direct bone conduction, "entails a lower stimulation velocity for a given hearing sensation." Snik et al, (1995) noted that a bone anchored hearing aid that is coupled with direct bone conduction, rather than conventional bone conduction has less harmonic distortion and more output above 500 Hz. This alternative direct bone conduction route is shown in Figure 1.

There are numerous reports in the literature attesting to the limitations of conventional bone conduction transduction, and no single solution will be appropriate (Wade et al, 1992; Proops et al, 1996; Negri et al, 1996). The manufacturers of the Audiant™ have attempted to use larger and stronger magnets (such as the neodymium iron boron magnet), but the limitation of this approach is inherent when using transcutaneous transduction. This is the main reason why the Audiant™ is not currently available.

Wade et al (1992) compared the aided gain from a group of Audiant™ and BAHA™ users.

Figure 7 (a, b, and c), show three transcutaneous vs. percutaneous histograms for 250 Hz and

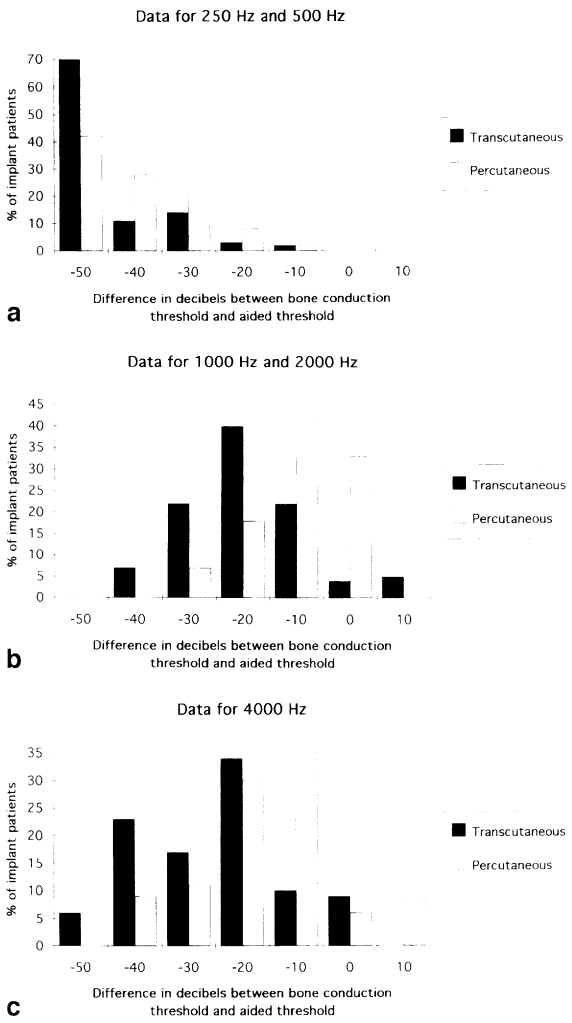

Figure 7 (a,b,c). Each histogram shows the percentage of implant patients who obtained the measured air-bone gaps on the abscissa, with the bone anchored hearing aid (Fig. 7a for low frequencies, 7b for mid frequencies, and 7c for high frequencies)

500 Hz (Figure 7a), 1,000 Hz and 2,000 Hz (Figure 7b), and 4,000 Hz (Figure 7c). The ordinate on each histogram shows the percentage of implant patients who obtained a measured air-bone gap when using one of the two types of bone anchored hearing aids. (Audiant™ in black and BAHA™ in gray). For example, a value of "0 dB" on the abscissa indicates that the conductive component (i.e., air-bone gap) was effectively closed in that particular frequency region. On the other hand, a value of "30 dB," indicates that even with the bone anchored hearing aid, a 30 dB air-bone gap was still present in a percentage of the implanted patients. In all three frequency regions, the percu-

taneous approach performed statistically better than the transcutaneous approach. However, it is clear that both approaches do not perform well for low-frequency sound energy transduction (i.e., the air-bone gap was not eliminated). It should be noted that these data were gathered with the stronger body worn Audiant™. The results would probably have been worse for one of the ear level Audiant™ hearing aids. Browning (1990), in examining the Audiant™, found similar results and also noted the ear level version provided relatively low-power.

The problem of closing the air-bone gap at 250 to 500 Hz stated for bone anchored hearing aids in Figure 7 is just as common for conventional bone conduction hearing aids. Increasing the effective mass of the transducer would improve the low-frequency response somewhat. However, there would be a tradeoff, with an increase in weight and associated patient discomfort.

Assessment Techniques

There are several assessment techniques that can be utilized to objectively verify the benefit provided by bone anchored hearing aids. The HCA 100 (previously called TU-1000) skull simulator has been developed by Hakansson and Carlsson (1989) and is used in conjunction with a hearing aid test system to verify electromechanical function of a bone anchored hearing aid. The HCA 100 skull simulator is shown in Figure 8. While it could be argued that an artificial mastoid would be appropriate for the assessment of the BAHA™, the HCA 100 simulator is based on a point source excitation rather than a small area excitation of the artificial mastoid. Since the BAHA™ transducer is a mechanical point source vibrator, this makes the HCA 100 a more appropriate simulator than an artificial mastoid.

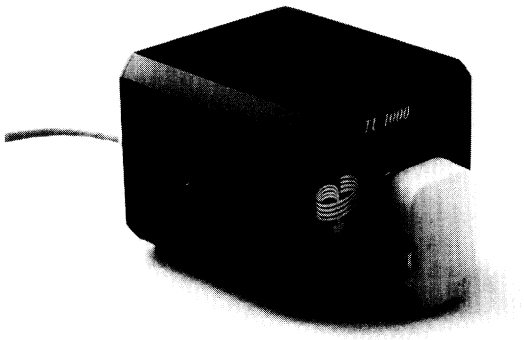

Figure 8. The HCA 100 skull simulator (previously called the TU-1000). Photograph courtesy of Nobel Biocare.

The HCA 100 can also be used to provide data for "functional benefit" to coupler transfer functions. Functional benefit is rather complex to quantify with bone anchored (as well as conventional bone conduction) hearing aids. Traditional measures of functional gain may not always be appropriate since a stimulus (for the unaided condition) may inadvertently assess the non-test ear or may assess a bone threshold via an alternate bone conduction route, if sufficiently intense. In addition, such a functional gain measure may inadvertently compare an air conduction route (unaided) with a bone conducted route (aided) and as such cannot be directly compared. While the aided measure can be easily defined in most cases the unaided component of functional gain is extremely difficult to quantify without encountering significant measurement error.

An alternative assessment scheme has been developed and was employed for the data shown in Figure 7. A measure of aided benefit was compared directly to the audiometric bone conduction threshold results. This difference is shown as the abscissa in Figure 7. Specifically, all aided thresholds were measured in sound pressure level (SPL) and converted to equivalent HL calibration with the use of a real ear measurement system. This was verified at the ear level using a Madsen IGO 1000 probe tube microphone system (Madsen Electronics, Inc., Copenhagen, Denmark). Essentially the verified sound field levels were converted to equivalent HL values using the minimum audible field conversions, so that they could be directly compared to audiometric bone conduction threshold values. A full explanation of this method of calibration is given in Wade et al (1992).

Other assessment techniques, such as aided speech in noise (Carlsson et al, 1986; Hakansson et al, 1990) have been developed. This test, allows for a direct comparison between the patient's previous air or bone conduction hearing aid and the bone anchored hearing aids. Specifically, sets of ten phonetically balanced, five word sentences, were used to determine signal-to-noise ratio (S/N) at the 50% discrimination point (Hagerman, 1982). The noise (presented from the same orientation as the speech) was derived from the energy properties of the test sentences, and therefore had a similar spectrum. Typical improvements were on the or-

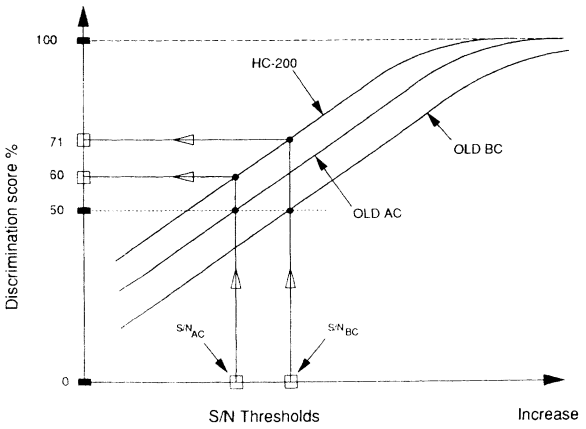

Figure 9. Improvements of the BAHA™ (HC-200) over patients' previous conventional air conduction or bone conduction hearing aids. This is shown as a lowering in the necessary signal-to-noise ratio in order to obtain 50% correct. Used with permission Hakansson et al (1990) and Annals of Otology, Rhinology, and Laryngology.

der of 2 dB in S/N ratio, with the bone anchored hearing aids yielding a 50% correct discrimination score at a S/N ratio of −1 dB, and the "previous amplification" requiring a S/N ratio of +1 dB. Statistically significant improvements were found consistently for the BAHA™ over conventional air and bone conduction amplification. Figure 9 shows such an improvement as a lowering in the necessary signal-to-noise ratio in order to obtain 50% correct with the BAHA™ (previously called the HC 200) over the patient's old air conduction and bone conduction hearing aids.

Proops et al (1996) found superior speech discrimination scores and better aided free field frequency specific thresholds with the BAHA™ over the Audiant™ and concluded that "Patients using the Audiant device who are not adequately rehabilitated should be considered for rehabilitation using a BAHA."

Potential Benefits

For those patients with chronic unresolvable otitis media, the absence of a hearing aid in the ear canal reduces the incidence of ear infections. As reported in Hakansson et al (1990), of 24 patients surveyed in a questionnaire, 22 patients now wearing the BAHA™ reported fewer ear infections than when wearing their previous air conduction hearing aids (with two reporting no difference). For those who previously wore an air conduction hearing aid, 16 out of the 24 reported improved sound quality (with five finding no difference, and three finding that the sound quality was worse). Finally, for those who previously wore a bone conduction hearing aid, 19 out of 27 noted improved wearing comfort (with four finding no difference and four noting that it was worse). As is typical, much can be learned from patients who report poor performance and/or poor wearing comfort and research continues (e.g., Holgers and Ringdahl, 1996) to improve the performance and comfort of the BAHA™.

Can BAHAs Be Used for Unilateral Hearing Loss?

Although no longer being marketed, the Xomed Audiant™ had been approved by the FDA since 1988 for use with patients with normal hearing in one ear and a conductive hearing loss meeting the established criteria in the other ear. (Hough et al, 1995). Browning (1990), in reporting the British experience with the Xomed Audiant™ with 18 patients, criticized such approval for a unilateral hearing loss suggesting that "the rationale for implanting such a patient is marginal at best." He was concerned that although it might be helpful when listening to someone on the side of the impaired ear in a background of noise, the Audiant™ would unfortunately stimulate both ears because of the minimal interaural attenuation. Weber and Roush (1991) also echoed Browning's reservation and felt that "there was insufficient data to predict the effectiveness of the Audiant for patients with normal hearing in one ear."

Welling et al (1991) attempted to accomplish such a fitting with a unilateral sensorineural hearing loss using the Xomed Audiant™. During acoustic neuroma surgery that would have left the ear without hearing, a magnet was installed for the Audiant™. They conclude that: "The proposed use of a bone conductor hearing aid for the unilaterally profoundly deaf has not. . .been shown to be effective." Reasons given were low power levels, poor inductive attraction and non-zero interaural attenuation values.

Given these reasons, since the output of the BAHA™ is significantly greater than the Audiant™, there is no reason to assume that a patient would not derive benefit from a percutaneous device such as the Nobel Biocare BAHA™. Indeed, seven patients with unilateral hearing losses (previous users of CROS amplification) have been

successfully fit in our own clinic. (Wade and Chasin, 1992). In this study three experiments were performed- masking level difference (MLD) assessment, binaural advantage in a skull simulator, and binaural changes in the performance-intensity function. Results indicate a 6.8 dB improvement on the MLD task, a 3.8 dB improvement on the binaural advantage in a skull simulator test, and a 2.1 dB improvement in the performance-intensity function. Perhaps the best measure of success, is that five years later these seven patients are routinely wearing their BAHA™ hearing aids.

A related question concerns the fitting of binaural bone anchored hearing aids and whether this is better than a monaural fitting, or a BICROS fitting. Mylanus et al, (1996) recently reported on the results of such an evaluation, and concluded that their patients preferred a binaural fitting over the BICROS and monaural fitting of the BAHA™. Specifically they found that directional hearing was still poor when the BICROS results were compared to the monaural BAHA™ fitting, but improved with a binaural fitting. It was also reported that the speech reception threshold in quiet improved 4 to 6 dB with the binaural fitting over a monaural fitting of the BAHA™.

The Last Word . . . ?

Bone anchored hearing aids appear to be an excellent alternative for those patients that have a significant conductive or mixed hearing loss and who are not functioning at an optimal level. Issues of wearing comfort for those with conventional bone conduction hearing aids and of repeated ear infections for those with air conduction hearing aids may lead a patient to consider this alternative. Although of great historical importance, many centers around the world have stopped implanting the Audiant™ device and in many cases have explanted the Audiant™ magnet and implanted the BAHA™ (Proops, 1996; Negri et al, 1996; Wade, 1996).

In my experience, a bone conduction PTA as little as 25 dB HL is felt to be too great and consideration of an Audiant™ would only be for patients with normal bone conduction thresholds (i.e., 0 dB HL to 5 dB HL) (Wade and Chasin, 1994). It should be pointed out that for such a hearing loss, barring any undue thickness of the skin and subcutaneous layers, the results between the Audiant™ and the BAHA™ should be similar. However, as presbycusis becomes a factor, the transcutaneous approach may no longer provide adequate output for the optimal hearing of the patient.

MIDDLE EAR IMPLANTS

The research on middle ear implants (MEI) parallels the work on bone anchored hearing aids in that there are two primary transduction mechanisms or approaches that are in use today- piezoelectric and electromagnetic. Unlike the field of bone anchored hearing aids however there are many parameters to study and control for with MEIs. Some of these factors are the location of the implant in the middle ear, orientation and physical characteristics of the implant and transducer, and the nature and degree of surgery for implantation. Whereas bone anchored hearing aids are routinely being fit on people and are essentially out of the research phase, many forms of MEIs are either still in the research stages with animals, or in prototype form with human subjects. The only exception to this are the piezoelectric implants currently being performed in Japan by Doctors Suzuki and Yanagihara (1989). In the not too distant future, the Vibrant Soundbridge System (Symphonix Devices, Inc.) may be approved for adults with sensorineural hearing loss. Currently 20 patients have been successfully implanted according to a strict protocol. Such a system transmits external sound transcutaneously to a transducer that has been surgically mounted onto the incus in the middle ear. It has been suggested that a better name for such an implant is a "soundbridge" rather than a MEI.

Unlike bone anchored hearing aids where a significant conductive component exists that prevents optimal use of an air conduction or bone conduction hearing aid, a MEI can be used for both a conductive and a sensorineural hearing loss. A motivating principle of mechanical transduction is that if the ossicles and/or cochlea can be driven directly, there will be improved fidelity without occlusion of the outer ear canal. That is, if the impedance characteristics of the tympanic membrane and ossicular structures can be ignored there will be improved sound transmission. In addition, since the energy is not converted back to an acoustic signal, feedback from this source is minimized. Some of the research programs, despite being based on sensorineural hearing loss, can have their results and devices applied equally well to patients with conductive or mixed hearing loss.

As stated by Goode et al (1995), a MEI is a hearing aid that is either partially or wholly im-

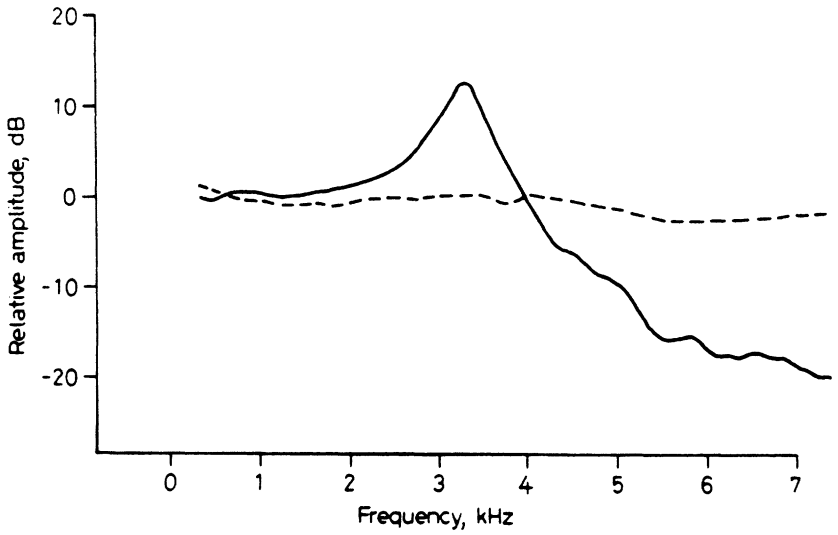

Figure 10. The upper frequency range for an unloaded piezoelectric bimorph crystal (solid line) is limited to 5,000 Hz, however when mechanically loaded (dashed line), an improvement in this frequency response is observed. Used with permission from Welling and Barnes (in Maniglia, (ed). 1995). Reprinted with permission from the Otolaryngologic Clinics of North America, Saunders, Philadelphia, PA.

planted in the middle ear cavity. While great strides are being made towards a wholly implantable hearing aid, (Lenkauskas, 1996; Spindel, 1996), the current state of technology is that all MEI projects currently underway have only partially implanted components.

Transducers

Piezoelectric

While no longer used with conventional hearing aids, this type of transducer can be remembered from our own crystal radio sets. This type of transducer has both electrical and mechanical properties. The electrical property is related to the electric field that is created as a result of its mechanical property of being able to deform under forces of stress and strain. The converse is also true; application of an electrical signal will create a mechanical deformation. Therefore, such a piezoelectric device can function both as a microphone and as a loudspeaker, albeit with differing efficiencies.

With MEIs, the piezoelectric bimorph crystal functions as an output transducer and depending on its implementation, may either be in direct or indirect contact with the ossicular chain. An advantage of such a method of transduction is its small size and simple design. Another advantage is that the crystal can be situated in several different locations in the middle ear without seriously compromising its function. However, its drawbacks involve having a high impedance and poor frequency response, especially in the lower frequencies. A commonly cited criticism of a piezoelectric transducer is that of a peaky frequency response due to the existence of a "resonant peak at its natural frequency." (Ko et al, 1995). However, Welling and Barnes (1995) noted that while this is true in isolation, when the crystal is loaded by attaching it to the stapes, the frequency response becomes flat. Fredrickson et al, (1995) argued that the upper frequency range for a piezoelectric bimorph crystal is limited to only 5,000 Hz, but when mechanically loaded, as shown in Figure 10, an improvement in this frequency response is observed.

Currently this form of transduction is used mostly in Japan by Dr. Suzuki, Dr. Yanagihara, and their colleagues. Dr. Dumon coordinates a program in France that utilizes piezoelectric transduction and Doctors Welling and Barnes have a program in the United States where a piezoelectric transducer is used to stimulate the semicircular canals. Each of these programs will be described in a following section.

Electromagnetic

Unlike the piezoelectric crystal, the orientation and distance from the transmitting coil of an electromagnetic transducer can seriously affect the strength and the frequency response. As the name suggests, an electromagnetic transducer is made up of two elements- a transmitting coil of wire and a receiving magnet. The movement of the receiving magnet varies according to the alternating current (AC) flux generated by the coil. In this way,

the AC signal, such as speech creates an analogous AC field in the coil that is then transduced through a magnetic field to the implanted magnet.

The first published work on electromagnetic transduction for hearing was by Wilska in 1935 (Goode, 1989) where 10 mg of soft iron pieces were placed on the tympanic membrane. A coil situated over the earcanal created a magnetic field that caused the iron pieces to vibrate in synchrony with the AC flux of the magnetic field. Wilska concluded that vibrations produced by the eardrum, whether created by a magnetic field and iron pieces, or acoustically, is perceived as the same.

In the 1950s, in order to produce an 80 dB SPL output at 1000 Hz, a coil current of 28,000 mA (RMS) was required (with a pinna location coil and a cunico magnet). With an improved coil location and better magnetic material, current systems can accomplish this same output with less than 3 mA (RMS) of current (with an earcanal location coil and a samarium-cobalt magnet). The transmitting coil location is the primary factor, with magnet type being of secondary importance.

Clearly, the shape and size of the transmitting coil as well as the mass and material composition of the receiving magnet can affect the sound that is ultimately transduced to the cochlea. Goode (1989) noted that in order to prevent loading of the ossicular chain, with a subsequent loss in the transmission of high-frequency energy, the magnet should have a mass of less than 50 mg. Some of these issues will be discussed further under the discussion of the various implant programs.

A governing relationship between magnetic field strength and distance between the coil and the magnet, is that field strength falls off as a cube of the distance. For example, if the transmitting coil is placed in the outer ear canal (such as in an in-the-ear shell), the transduced strength would be greater if the magnet is on the umbo than if on the more medial stapes. Clearly this would not be as great an issue if the transmitting coil was also implanted into the middle ear cavity, as is the case in some implant programs.

An inherent characteristic of all electromagnetic induction systems is that with each octave increase, a 6 dB lower output current is created by the coil, given a similar input voltage. That is, ". . . the inductive reactance of the coil increases with frequency." (Goode, 1989). The amplifier must then be designed to provide additional output in the higher frequency range to counter this phenomenon.

The third factor that has more to do with the movement of the ossicular chain than electromagnetic transduction per se, is the high-frequency vibration of the ossicular chain. Goode et al (1989) and Goode (1995) noted that the tympanic membrane is rather inefficient above 1,000 Hz and the ossicular chain undergoes a progressively increasing rotation as the vibration becomes more medial. It was concluded that a better high frequency response would be achieved if the magnet was to be placed on the stapes, rather than on the more lateral umbo.

A trade-off relationship appears to exist then with electromagnetic transduction. As the magnet is situated more medially (away from the coil), the signal strength is poorer, but the high frequency response is better. This trade-off underscores, and to a great extent explains, the differing philosophies of the various implant programs around the globe. Table 1 summarizes the features of both types of transducers currently in use for MEI programs.

Implant Programs

The section will provide an overview of the major implant programs around the world by researcher, affiliation and location. The list is not complete as many centers may have an MEI component as part of a much larger middle ear reconstructive program. In addition, there have been many historically important MEI programs that either have concentrated on one small aspect of the implant or whose team is no longer actively publishing research. A discussion of some of these early programs can be found in Goode (1989) and Goode et al, (1995). A summary of the implant programs, along with their various features will be shown in Table 2 in the conclusion section.

Table 1: Summary and comparisons of some of the features of both types of transducers currently in use for MEI programs.

	Piezoelectric	Electromagnetic
Impedence level (ohms)	10^{7-9}	10^{2-3}
Overall frequency resp.	good	good
Size/volume	small	medium
Packaging	difficult	moderate
Transduction	indep. of coil	dep. on coil

Piezoelectric Based Programs

The different programs utilizing piezoelectric transduction base their orientation and philosophies on whether the ossicular chain should be altered. While the Japanese approach is non-reversible and involves a significant amount of modification to the ossicular structures, the American and French programs, attempt to preserve an intact ossicular chain.

Suzuki, Kodera, Nagai, and Yabe (Teikyo University, Japan) and Yanagihara, Gyo, and Hinohira (Ehime University, Japan)

Most of the historical development of piezoelectric transduction for hearing aids occurred at Teikyo University under the guidance of Dr. Jun-Ichi Suzuki and at Ehime University under the direction of Dr. Naoaki Yanagihara. In 1978, funding was obtained from the Japanese government to develop a MEI program as an alternative to middle ear surgery in patients with chronic serous otitis media. (Suzuki and Yanagihara, 1989; Gyo, 1989). Since 1984, this program has implanted more than 60 patients in conjunction with development and technical support from Rion Company, Ltd., Tokyo, Japan. (Yanagihara et al, 1995). The Rion Company, Ltd. hearing aid system has been commercially available since 1993.

This MEI is designed for patients with conductive or mixed hearing loss up to 50 dB HL bone conduction average at 500 Hz, 1000 Hz, and 2000 Hz. The other ear must have at least a moderate to severe hearing loss and there should be a demonstrated improvement in an intraoperative vibratory hearing test. In this test a vibrator is temporarily glued onto the stapes and connected to an audiometer. The patient, who is under a local anesthetic, responds to pure tones in the same manner as conventional audiometry. These patients should be able to perform better than those results that would be obtained with normal middle ear reconstructive surgery. If this is not the case, the implant surgery is terminated prior to any further drilling or removal of ossicular structures. An important aspect of this approach is that the surgery involves the destruction of the attic and mastoid areas, as well as the removal of the incus, and as such, is not a reversible procedure.

Prime candidates are those patients with congenital malformations of the middle ear and those with chronic middle ear disease that has not responded adequately to medical and/or surgical intervention. In the case of chronic middle ear disease, the operation may be performed in several stages, as the health of the middle ear must be stable. Because this device is appropriate for those who possess up to a 50 dB HL bone conduction average hearing loss, patients with significant noise exposure and/or presbycusis, in addition to middle ear pathology may still be candidates.

In this program the piezoelectric transducer of the Partially Implanted Hearing Aid (PIHA) (also called the Partial Middle Ear Implant [P-MEI]), is connected directly to the stapes. This receives a direct transmission from the output of a secondary coil implanted under the skin on the mastoid. This secondary coil is adjacent to an external primary coil situated on the mastoid region, that is encased in a behind-the-ear hearing aid case (Rion Company, Ltd.). The primary external coil transduces the signal through induction to the implanted secondary coil. In addition to the external coil, the hearing aid case also houses the microphone, amplifier, and battery. Because the hearing aid case is external, adjustments can be made for overall gain, output and frequency response. Figure 11 shows a schematic of this system. (Yanagihara et al, 1995). Suzuki et al, (1995) noted that a percutaneous or a ". . . direct wiring . . .would afford an additional gain of about 20 dB. Also, it would save energy that is otherwise consumed by magnetic induction . . ."

Suzuki et al (1994, 1995) examined the long-term results of this program and found that hearing thresholds were stable up to almost six years post implant; the longest of their follow-up patients. Not only was there improved air conduction thresholds as a result of the MEI, but the bone conduction thresholds also were improved by 5 to 10 dB in the 500 Hz to 4000 Hz region. The authors attributed this to the differential loading of the stapes as a result of the implant. If "number of hours per day worn" can be used as an indicator of success, in a study of 19 partial MEI wearers, 17 used the device all day, with two using it occasionally. (Suzuki et al, 1994). Yanagihara et al (1995) found in a seven year follow-up of 64 cases that the MEI failed or was removed in six cases and that these were mostly the early ones. The manufacturer of the implant (Rion Company, Ltd.), based on accelerated aging tests, notes that the components should last for at least 20 years before replacement is necessary.

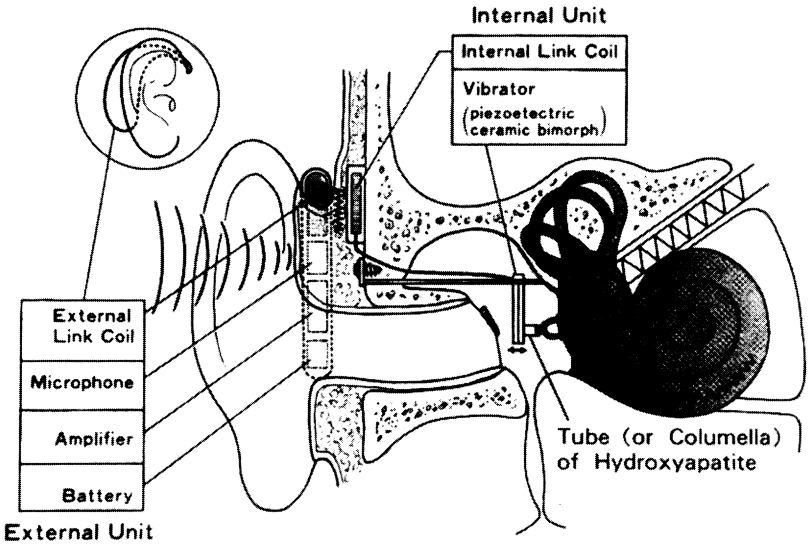

Figure 11. The piezoelectric transducer of the Partially Implanted Hearing Aid (PIHA) (also called the Partial Middle Ear Implant (P-MEI)), as used by Suzuki and Yanagihara, in Japan. Used with permission from Yanagihara et al, (in Maniglia, (ed). 1995). Reprinted with permission from the Otolaryngologic Clinics of North America, Saunders, Philadelphia, PA.

Welling and Barnes (Ohio State University College of Medicine, Columbus, Ohio)

As a modification to the work of Doctors Suzuki and Yanagihara, the program of Bradley Welling and Douglas Barnes is designed to preserve the ossicular chain with MEI surgery. Preservation of the ossicular chain would have several potential advantages; (a) reversible surgery due to a less involved approach; (b) improved transmission to the cochlea with an intact ossicular chain making the MEI appropriate for those with significant sensorineural hearing losses, and (c) the possibility of using the individual's own tympanic membrane as the receiver of an acoustic signal from an ITE or ITC hearing aid.

In the Welling and Barnes program, a piezoelectric transducer is attached through a fenestra to the superior semi-circular canal of the inner ear. The sound conduction pathways of the middle ear are therefore left intact. Such an approach is not new and served as the basis for the fenestration operation for otosclerosis (Lempert, 1938). Success has been reported using the cochlear microphonic (CM) in conjunction with coherence functions as measurement tools. The CM technique has been shown to be of high reliability in a very early study of MEIs. (Mahoney and Vernon, 1974).

While this approach is still experimental and has been using the cat as the animal model, Welling and Barnes (1995) report on one case with a human subject. After receiving regulatory approval, a temporary implant was performed during surgery involving the ablation of the posterior semicircular canal for relief of intractable positional vertigo. An intraoperative audiogram that used a piezoelectric driver attached to a fenestra in the posterior semicircular canal showed excellent results (lower than 1.5 volts) between 500 Hz and 2,000 Hz. The speech discrimination score, presented at an average conversational level was 84% with only 0.7 volts applied. The post-operative audiogram was within 5 dB of the pre-operative audiogram after a 3 week recovery period.

Dumon, Zennaro, Aran, and Bebear (University of Bordeaux, Bordeaux, France)

Dumon and his colleagues have been impressed by the structural simplicity of the piezoelectric approach. Desiring to preserve the ossicular chain, these researchers utilize a piezoelectric bimorph crystal inserted into the incudo-stapedial joint (at the head of the stapes), a position that has near optimal mechanical conditions and one that can be removed with relative ease and without destruction of the ossicular chain. (Dumon et al, 1993; Dumon et al, 1995). Figure 12 shows a schematic of this approach.

The test model was the guinea pig and to date all testing has been performed on this animal. The auditory nerve evoked potentials (AEP) served as the assessment tool with measured output levels ranging from 85 dB SPL to over 110 dB SPL. Because of the high levels that can be transduced without noticeable discomfort the researchers are confident that future applications of this device will include the treatment of patients with sensorineural hearing loss.

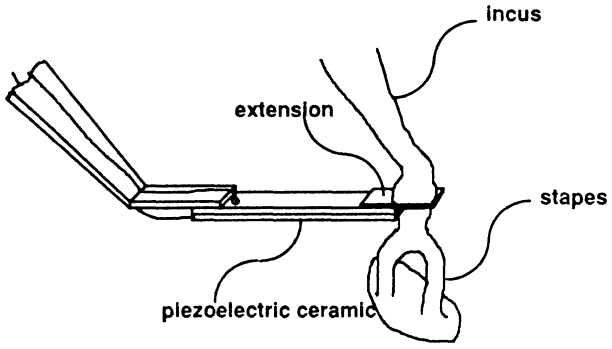

Figure 12. A piezoelectric bimorph crystal inserted into the incudo-stapedial joint (at the head of the stapes). This position has near optimal mechanical conditions and can be removed with relative ease without destroying the ossicular chain. Used with permission from Dumon et al, (in Maniglia, (ed). 1995). Reprinted with permission from the Otolaryngologic Clinics of North America, Saunders, Philadelphia, PA.

Currently this MEI is not for use with human subjects, but the team is redesigning the hardware for such a use. They are considering using a percutaneous transduction mechanism because of its superior mechanical transduction properties.

Electromagnetic Based Programs

Unlike the piezoelectric approach, the electromagnetic form of transduction may have a more "day-to-day" application. Quoting from Goode (1989): "The encapsulated magnet can be inserted at the time of tympanomastoid or middle ear surgery if it appears that ossicular reconstruction is not likely to restore thresholds . . .. If a satisfactory hearing level is not achieved following surgery, the electromagnetic induction hearing aid could be used to drive the magnet in the prosthesis, correcting any residual conductive loss." That is, if during routine middle ear surgery that has a questionable outcome, a magnet may be implanted that may serve as an effective transducer in conjunction with an external coil that may be used in the future. If not used, the implanted magnet will yield no negative effects.

Spindel and his colleagues clearly demonstrated in a series of studies that magnetic ossicular stimulation yielded similar results to acoustic stimulation that would be obtained with conventional hearing aids. Examination of amplitude and latency ABR results for both types of transduction, yielded no significant differences with correlations in excess of 0.94. (Spindel et al, 1991; Spindel et al, 1995).

Whereas the various piezoelectric programs differ based primarily on the nature of the post-surgical ossicular chain, the various electromagnetic transduction programs differ primarily on the location of the implanted magnet (and in some instances, the coil). The following overview of the programs will be discussed according to magnet location.

Baker, Wood, and Hough (The Hough Ear Institute, Oklahoma City, Oklahoma):

The credit for delineating the advantages and disadvantages of the various magnet locations and magnet shapes belong primarily to this group of researchers. During routine stapedectomies, magnets were intraoperatively placed at various locations on the ossicular chain while being subjected to magnetic fields from an external coil. Varying comments of sound fidelity were provided by their patients.

After experiments with five subjects in 1988 who had various sensorineural hearing loss configurations, it was concluded that the incudo-stapedial joint appeared to be the optimal location for the magnet and that the magnet should be a donut shape (annular). In their program, the driving coil was in the external ear canal. Despite the greater distance from the coil (as compared with a umbo or tympanic membrane position), all the subjects were found to have improved "aided" thresholds between 500 Hz and 4000 Hz. Gain of up to 40 dB were obtained, making such a device quite adequate for those with sensorineural hearing loss, as well as for those with significant conductive hearing loss. Because of the more medial location on the ossicular chain excellent high frequency gain of up to 40 dB (between 3000 - 4000 Hz) was also obtained. An important aspect of this ossicular chain position is that the magnet can be surgically removed with no residual effect.

Unfortunately, approximately three months after these five subjects were implanted, their responses degraded to pre-implant levels. The magnets were removed and analyzed. The composition

of the magnets was neodymium-iron-boron and it was found that prior to implant, moisture had affected the iron in the magnet causing a slow disintegration with a loss of magnetic ability. As a result of this, the material was changed to a samarium-cobalt rare earth magnet and the problem was alleviated. Because the samarium-cobalt magnets have poorer magnetic strength than the previous iron based magnets they had to be larger. While the mid frequency gain was quite adequate the high frequency response was poor. The researchers attributed this to a loading effect created by the larger magnet.

It is suspected that the solution may be a stronger coil and a smaller samarium-cobalt magnet (less than 50 mg). Another solution may be to encase an iron based magnet in a non-reactive casing such as stainless steel or titanium (such as that used by Maniglia et al, 1995). This would protect against moisture induced degradation effects.

Fredrickson, Coticchia, and Khosla (Washington University School of Medicine, St. Louis, Missouri)

The primary design for this implant is for those with sensorineural hearing loss, although there is nothing inherent in the design that would obviate its use for those with a significant conductive component. This program (along with that of Maniglia's discussed below), uses a complex series of coils that transduces its energy to an implanted "electro-magnetic motor". This approach was first described in Fredrickson et al (1973).

The primary external coil couples transcutaneously with a secondary coil implanted just beneath the postauricular skin. This implanted coil transduces energy to a smaller third coil that energizes an electromagnetic motor. The motor, initially encased in stainless steel and more recently titanium, drives a probe that is directly connected to the Incus. Early implant surgery used a small clip-on attachment to the incus, but more recent implants involve the use of a laser hole. The mechanical advantage of such a system is a better impedance matching with a more efficient transmission of sound. Outputs have been measured to 140 dB SPL (presumably used with some output limiting circuitry) and the response is reported to be flat up to 10000 Hz. (Fredrickson et al, 1995; Fredrickson, 1996).

The animal model in this program's research is the rhesus monkey and pre- and post-implant assessment was performed with evoked response and distortion product otoacoustic emission measurements. (Fredrickson et al, 1995; Park et al, 1995). Results indicate that the implant does not load the ossicular chain and subsequently does not create a high frequency conductive hearing loss. Histologically, after a two year study of rhesus monkeys, they have found no damage to the cochlea or other peripheral auditory structures.

The Fredrickson group has recently performed experiments on two patients (sensorineural hearing loss of 70 dB HL) using a non-invasive procedure by contacting the tympanic membrane through the external ear canal, superior to the umbo. There are reported improvements of up to 19% in word recognition scores when compared to the contralateral ear using standard insert earphones. (Fredrickson, 1996). Fredrickson and his colleagues are in the process of obtaining approval from the FDA for use on a series of patients with a sensorineural hearing loss.

Maniglia, Ko, Rosenbaum, Falk, Zhu, Frenz, Werning, Masin, Stein, and Sabri (Case Western Reserve University School of Medicine, Cleveland, Ohio)

This implant program has been in progress since 1986 and has based its work on the cat as an animal model. The FDA has recently approved a study to perform clinical trials on human subjects with sensorineural hearing loss (Maniglia, 1996).

This program's external to internal coil transduction system is similar to that of the Fredrickson program in that there are a series of coils that transduce the environmental sound to an implanted coil. As is the case with the Fredrickson program, the intent of this implant program is for patients with sensorineural hearing loss. This MEI program utilizes a magnet glued onto the incus, but unlike other implant programs, the coil is situated in the attic. Subsequently a relatively complex surgery is required that includes both a mastoidectomy and an atticotomy. Every effort is made to preserve an intact ossicular chain. In addition, a skin pocket is created behind the ear that holds the external coil. The skin pouch requires that the external coil be worn frequently so that its dimensions will not shrink. Typically the size of the skin pouch stabilizes after about six months. (Maniglia, 1989; Maniglia et al, 1995).

The magnetic material that was initially used was samarium-cobalt, but due to its rather low

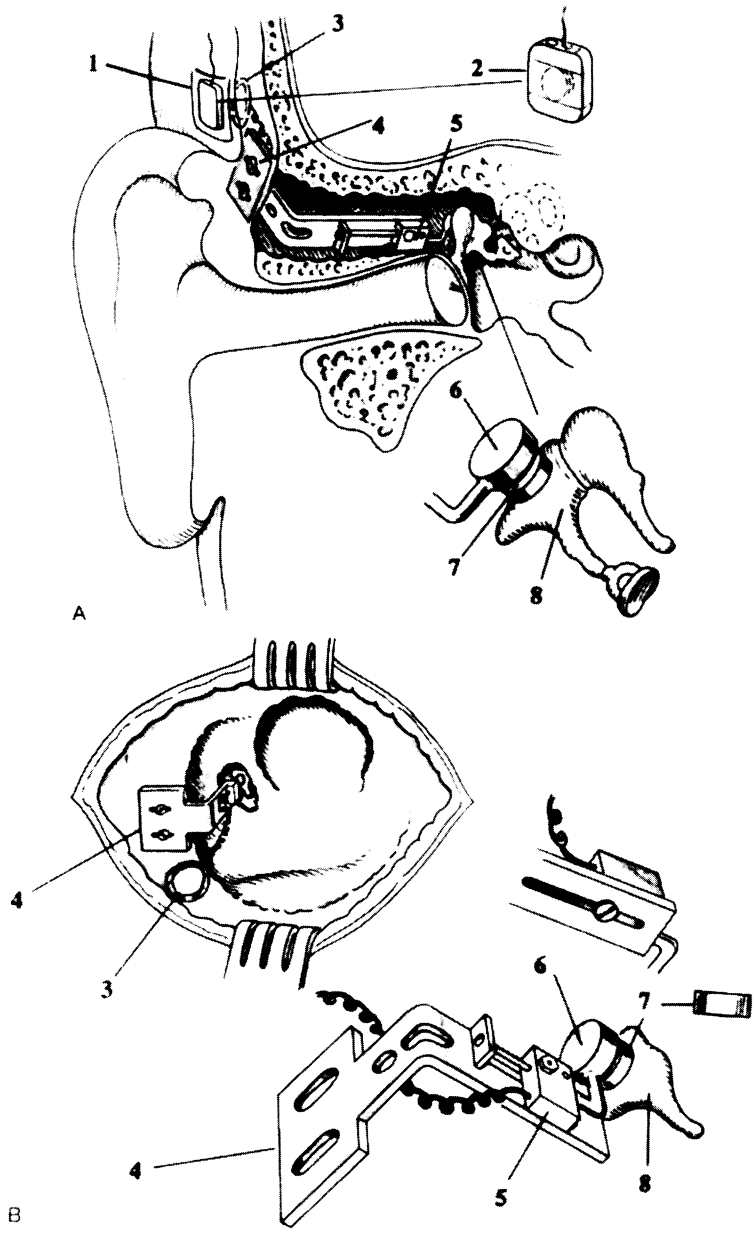

Figure 13. Schematic of the essential parts of the implant used by Maniglia and his colleagues. Used with permission from Maniglia et al (in Maniglia, (ed). 1995). Reprinted with permission from the Otolaryngologic Clinics of North America, Saunders, Philadelphia, PA.

magnetic strength, the researchers switched to the more powerful neodymium-iron-boron magnet. In order to avoid the moisture contamination problem reported by the Hough Ear Institute, the iron based magnet was encased in a titanium shell. In its current form, the magnet and shell weigh less than 30 mg, and as such, should not affect the vibration of the ossicular chain. Using radio frequency (RF) telemetry, an average gain of 35 dB was obtained. (Maniglia et al, 1995). Figure 13 shows a schematic of the essential parts of the implant.

This implant program uses an innovative coil design that has an air-filled core. When the core does not contain a solid material, only the "push force" is transmitted. There is no transmission while it is idling. This results in an improved signal-to-noise ratio for the transmitted signal with potentially improved sound quality characteristics. While it is true that an iron-core coil would be significantly stronger, because of the close proximity of the coil to the implanted magnet, strength is not an issue. However, the maximum output was limited to 100 dB SPL for safety reasons.

Spindel, Lambert, and Ruth (University of Virginia School of Medicine, Charlottesville, Virginia)

Unlike the previous magnet locations from other implant programs, this program's magnet location is situated on the round window (as indicated by this device's name: Round Window ElectroMagnet [RWEM]). The primary motivation for this location is to avoid the ossicular chain so that loading will not become an issue. In addition, sound from the environment can be transduced through both the electromagnetic route to the round window, and through the normal middle ear pathways.

The RWEM implant that most of the research is based on, utilizes an external coil. Because of its relatively large distance from the implanted magnet special care was taken by the researchers to optimize the coil's characteristics for both strength and frequency response. Other forms of the RWEM implant locate the coil and associated electronics in the mastoid region. A schematic of this approach is shown in Figure 14.

Spindel and his colleagues, in using amplitude and latency measures from ABR on guinea pigs, found that the nature and degree of electromagnetic energy reaching the cochlea was similar to that of the acoustic route normally used with hearing. (Spindel et al, 1991, Spindel et al, 1995; Spindel, 1996). All of the guinea pigs had normal hearing. This group will be using the RWEM implant on guinea pigs with an induced hearing loss, in an attempt to ascertain whether such a device will be appropriate for those with sensorineural hearing loss.

Like other implant programs, in the future the RWEM implant has the potential to be a totally implanted MEI hearing aid. The microphone could be surgically situated just inferior to the ear canal with the processor and transmitting coil in the mastoid region, adjacent to the magnet on the round window. (Spindel, 1996).

Kartush and Tos (Michigan Ear Institute, Farmington Hills, Michigan)

The original intent of this project was to attach a magnet either to the lateral side of the tympanic membrane or to the medial side of the tympanic membrane. A magnet in these locations would be physically close to a transducing coil mounted in an in-the-ear hearing aid shell in the ear canal, with the result that a strong signal could be generated. Both of these approaches could be used for the treatment of sensorineural hearing loss. However, because the FDA did not want to approve a study that would necessitate middle ear surgery where no pathology exists for research purposes, the program was expanded to investigate those with mixed hearing loss. Kartush and Tos named this implant, the electromagnetic ossicular augmentation device, because it was designed to utilize the natural behaviour of an intact ossicular chain. The target patient group would be those

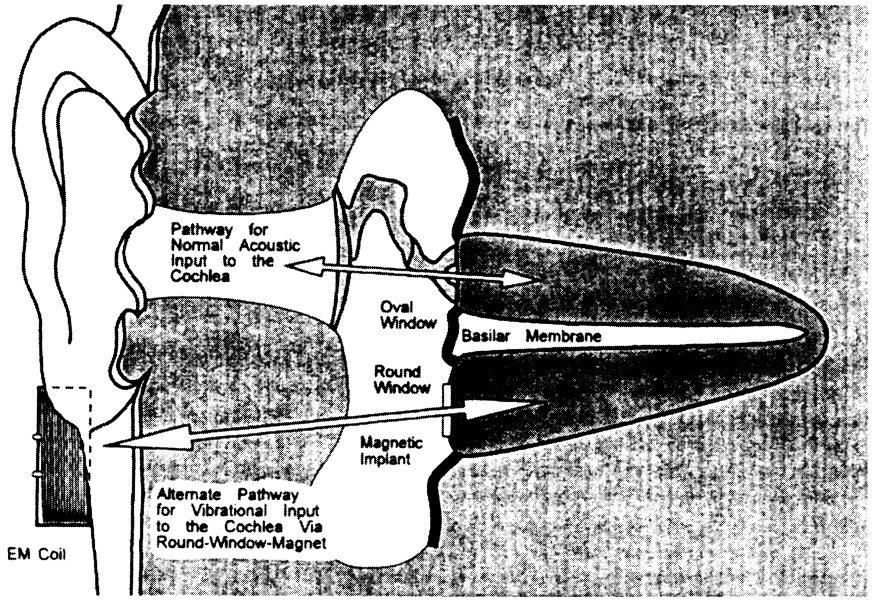

Figure 14. Schematic of the Round Window Electromagnetic implant (RWEM) showing the transduction of energy, used by Spindel and his colleagues. Used with permission from Spindel et al, (in Maniglia, (ed). 1995). Reprinted with permission from the Otolaryngologic Clinics of North America, Saunders, Philadelphia, PA.

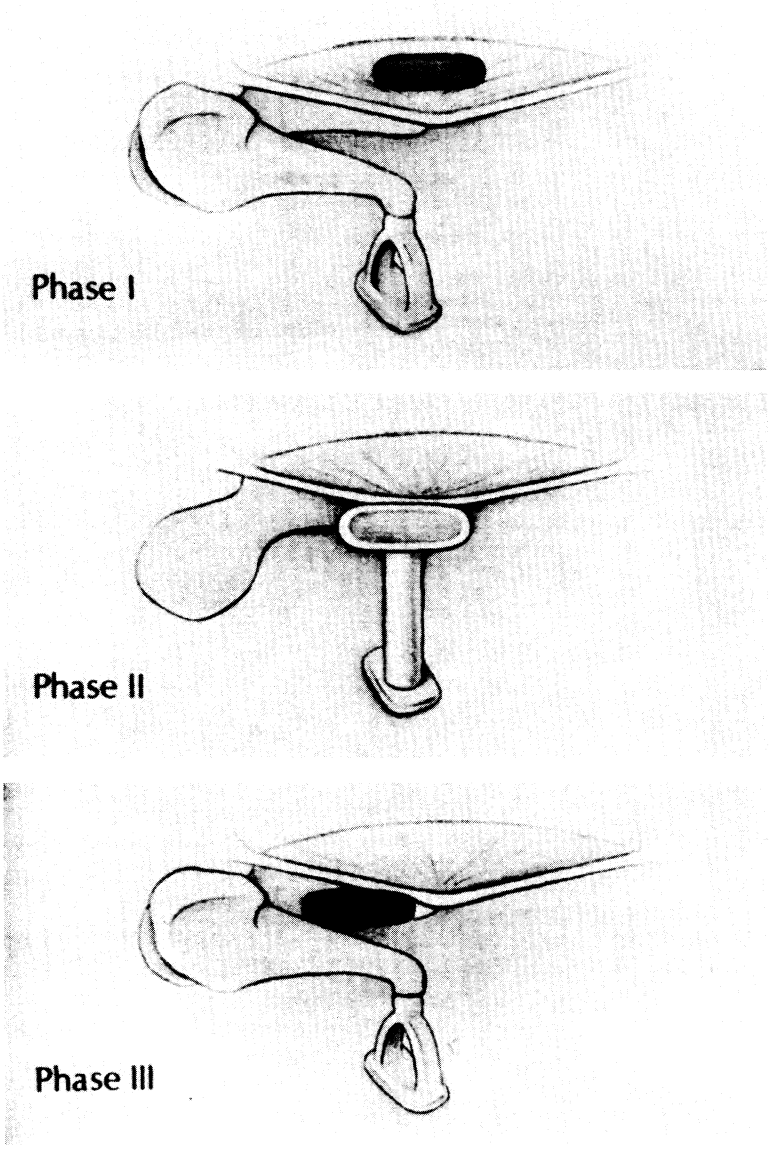

Figure 15. Kartush and Tos refer to this implant as an electromagnetic ossicular augmentation device. All three phases are shown (see text). Used with permission from Kartush and Tos (in Maniglia, (ed). 1995). Reprinted with permission from the Otolaryngologic Clinics of North America, Saunders, Philadelphia, PA.

with up to a 70 dB sensorineural hearing loss, with hearing no better than 40 dB HL at 4000 Hz, and no better than 30 dB HL at 500 Hz.

An advantage of this approach is the minimal amount of surgery that is required and the maintenance of the function of the ossicular chain. In this sense, the surgery is reversible. Kartush and Tos referred to the approach with the magnet attached to the lateral side of the tympanic membrane as Phase I, and with the magnet attached to the medial side of the tympanic membrane as Phase III. The FDA requirement (that would be useful for those patients with mixed hearing loss) is referred to as Phase II. All three phases are shown in Figure 15.

The results of Phase I on six patients were very positive. The presence of the magnet (weighing between 35 to 46.4 mg) on the tympanic membrane did not measurably alter the hearing. Functional gain in the mid frequencies for six patients increased by up to 17.5 dB over that which they were obtaining from their conventional hearing aids. In addition, on average there was a 10.84 dB improvement in the speech reception threshold over that found with the patient's conventional hearing aids. (McGee et al, 1991). The results of Phase II were more varied, but still positive. At this point in time, approximately 70 patients have been implanted. Phase III has been approved by the FDA for up to ten patients. As of 1995, three

patients had been implanted (with the magnet encased in titanium) and while results are variable, functional gains of 30-40 dB have been obtained. (Kartush et al, 1995). Recently however, due to poor overall performance, corporate funding has been withdrawn and the program has been closed.

CONCLUSION

The various characteristics of the percutaneous versus transcutaneous bone anchored hearing aids were discussed. While the advantage of the transcutaneous approach such as that used with the Audiant™ is one of cosmetics (i.e., no abutment protruding through the skin), the improved transduction (by up to 20 dB) of a "hard wired" percutaneous implant such as the BAHA™ appears to be a much more significant factor in the successful fitting of these patients. Even though researchers are working to improve the output characteristics of the Audiant™ (Dyer et al, 1996), the lack of flexibility and output may always limit its clinical applicability. While of great historical importance, the limitations of the Audiant™ are quite significant, and any future bone anchored hearing aid will probably be required to use a percutaneous approach, such as the BAHA™.

However, when it comes to middle ear implants, the transcutaneous approach appears to be quite adequate. Most of the researchers in the field do admit to a potential improvement from a percutaneous approach, but because of better sensitivity of the implanted magnet or coil(s), the transduction is sufficient. With the eventual introduction of wholly implantable MEIs, the connection will undoubtedly be "hard wired" in any event, and will be necessary to off-set the minimal loss of energy created by the attenuation created by skin or cartilage between the environment and the internal microphone.

The choice of the piezoelectric or electromagnetic MEI is not as clear, and Table 2 compares various aspects of the piezoelectric and electromagnetic based programs that have been discussed.

Historically one could say that piezoelectric transducer based programs used surgery that was not reversible, and the opposite was true of electromagnetic transducer based programs. However, due to the pioneering work of Welling and Barnes in the United States, as well as Dumon and his colleagues in France, this is certainly not the case. In addition, technical criticisms of the piezoelectric transducer such as possessing a peaky frequency response, are invalid since the response flattens out when it is loaded by the ossicular chain. It is suspected that in the future, because of the small transducer size, more piezoelectric based programs may come into existence.

This is an extremely dynamic field and there is rarely a month that passes without the granting of a new patent for some aspect of an IHA. Even though it may be many years, it is suspected that a certain proportion of those patients who are candidates for cochlear implants may instead be candidates for IHAs. It is however, doubtful if an IHA would be used for cosmetic concerns, especially since the introduction of CIC hearing aids.

Table 2: A summary of the various characteristics of the MEI implant programs.

Researcher	Country	Transduction	Location	Reversible	Subject
Suzuki/Yanagihara	Japan	Piezoelectric	Stapes	No	Humans
Welling & Barnes	U.S.A.	Piezoelectric	Semi-circ. canal	Yes	Cat
Dumon et al.	France	Piezoelectric	Incudo-stapes	Yes	Guinea pig
Baker et al.	U.S.A.	Electromagnet	Incudo-stapes	Yes	Humans
Fredrickson et al.	U.S.A.	Electromagnet	Incus/malleus	Yes	Monkey
Maniglia et al.	U.S.A.	Electromagnet	Incus	No	Cat
Spindel et al.	U.S.A.	Electromagnet	Round window	Yes	Guinea pig
Kartush & Tos	U.S.A.	Electromagnet	TM	Yes	Humans

APPENDIX

Some excellent references exist in the literature on this topic and the interested reader is referred to:

J. Suzuki (ed). 1988. Middle Ear Implant: Implantable Hearing Aids. *Advances in Audiology* 4. Basel. Karger.

A. J. Maniglia (ed). 1995. Electronic Implantable Devices For Partial Hearing Loss. *The Otolaryngology Clinics of North America* 28(1).

Yanagihara, N., Suzuki, J-I. (eds). 1992. Transplants and Implants in Otology II. Amsterdam: Kugler/Ghedini.

Carlsson, P. 1990. On Direct Bone Conduction Hearing Devices- Advances In Transducer Technology And Measurement Methods. Technical Report No. 195, Department of Applied Electronics, Goteborg, Sweden: Chalmers University of Technology.

Mylanus, E.A.M. 1994. The Bone Anchored Hearing Aid, Clinical And Audiological Aspects. Dutch: Proefschrift Nijmegen.

ACKNOWLEDGMENTS

The author would like to acknowledge David Fabry, Douglas Miller, Michael Valente, and David Preves for their helpful editorial suggestions. In addition, a special acknowledgment goes to Dr. Phillip Wade, without whose interest I would not be able to have written this manuscript.

REFERENCES

Branemark PI. (1985). Introduction to osseointegration. In: Branemark P-I., Zarb G., Albreksson T, (eds). *Tissue-Integrated Prosthesis*. Chicago, IL: Quintessence Publishing Co., Inc.

Browning GG. (1990). The British experience of an implantable, subcutaneous bone conduction hearing aid (Xomed Audiant). *J Laryng Otol* 104:534-538.

Carlsson P. (1990). On Direct Bone Conduction Hearing Devices- advances in transducer technology and measurement methods. Technical Report No. 195, Department of Applied Electronics, Chalmers University of Technology, Goteborg, Sweden.

Carlsson P, Hakansson B, Rosenhall U, Tjellstrom A. (1986). A speech-to-noise ratio test with the bone-anchored hearing aid: A comparative study. *Otolaryng-Head Neck Surg* 94(4):421-426.

Campos CT. (1988). A chronology of an implantable bone conductor hearing device. *Hear Instrum* 39(11): 36-38.

DiToppa JC, Liepert D. (1993). Bone Anchored Hearing Aids: The Edmonton Experience. Technical paper presented at Craniofacial Osseointegration Canada '93, Lake Louise, Alberta, Canada.

Downing M. (1996). A bone-anchored percutaneous connector system for neural prostheses applications. In: *2nd International Symposium on Electronic Implants in Otology and Conventional Hearing Aids*, Goteborg, Sweden: Nobel Biocare.15.

Dumon T, Zennaro O, Charlet de Sauvage R, et al (1993). Implants d'oreille moyenne: Developpement d'un prototype humaine. *Rev. Laryngol. Otol. Rhinol. (Bord)* 114:147.

Dumon T, Zennaro O, Aran J-M, Bebear J-P. (1995). Piezoelectric Middle Ear Implant Preserving the Ossicular Chain. In Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryngologic Clinics of North America*, Philadelphia, PA: W.B. Saunders Company, 173-188.

Dyer Jr RK, Collier MA, Dormer KJ, Gan RZ, Depphibal WY, Nakmali D. (1996). Evaluation of the Audiant™ bone conductior using laser doppler interferometry. In: *2nd International Symposium on Electronic Implants in Otology and Conventional Hearing Aids*, Goteborg, Sweden: Nobel Biocare, 9.

Fredrickson JM. (1996). personal communication.

Fredrickson JM, Tomlinson DR, Davis ER, Odkvist LM. (1973). Evaluation of an electromagnetic implantable hearing aid. *Can J Otol* 2:1.

Fredrickson JM, Coticchia JM, Khosla S. (1995). Ongoing Investigations into an Implantable Electromagnetic Hearing Aid for Moderate to Severe Sensorineural Hearing Loss. In: Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryngologic Clinics of North America*, Philadelphia, PA: W.B. Saunders Company, 107-120.

Gates G, Hough J, Gatti W, Bradley W. (1989). The Safety and Effectiveness of an Implanted Electromagnetic Hearing Device. *Arch. Otolaryngol. Head and Neck Surg* 115:924-930.

Goode RL. (1989). Current Status of Electromagnetic Implantable Hearing Aids. In: Otology-Current Concepts and Technology, *The Otolaryngologic Clinics of North America*, Phiadelphia, PA: W.B. Saunders Company, 201-209.

Goode RL. (1995). Current status and future of implantable electromagnetic hearing aids. In: Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryngologic Clinics of North America,* Philadelphia, PA: W.B. Saunders Company, 141-146.

Goode RL, Nakamura K, Gyo K, Aritomo H. (1989). Comments on "Acoustic transfer characteristics in human middle ears studied by a SQUID magnetometer method" [J. Acoust. Soc. Am. 82, 1646-1654 (1987)]. *J Acoust Soc Amer* 86(6):2446-2449.

Goode RL, Rosenbaum ML, Maniglia AJ. (1995). The History and Development of the Impantable Hearing Aid. In: Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryn-*

gologic Clinics of North America, Philadelphia, PA: W.B. Saunders Company, 1-16.

Granstrom G, Tjellstrom A. (1996). Application of the bone anchored hearing aid (BAHA) in malformed children. In: *2nd International Symposium on Electronic Implants in Otology and Conventional Hearing Aids*, Goteborg, Sweden: Nobel Biocare, 24.

Gyo K. (1989). The partial middle ear implant. *Audiology in Practice* VI/I:4-6.

Hagerman B. (1982). Sentences for testing speech intelligibility in noise. *Scan Audiol* 11:79-87.

Hakansson B, Carlsson P. (1989). Skull simulator for Direct Bone Conduction Hearing Devices. *Scan Audiol* 18:91-98.

Hakansson B, Liden G, Tjellstrom A, Ringdahl A, Jacobsson M, Carlsson P, Erlandson B-E. (1990). Ten Years of Experience with the Swedish Bone-Anchored Hearing System. *Ann Otol Rhinol & Laryngol* Suppl. 151, 99(10), Part 2.

Holgers K-M, Tjellström A, Bjursten LM, Erlandsson BE. (1988). Soft Tissue Reactions Around Percutaneous Implants: A Clinical Study Of Soft Tissue Conditions Around Skin-Penetrating Titanium Implants For Bone-Anchored Hearing Aids. *Amer J Otol* 9:56-59.

Holgers K-M, Ringdahl A. (1996). Benefits and shortcomings with BAHA. In: *2nd International Symposium on Electronic Implants in Otology and Conventional Hearing Aids*, Goteborg, Sweden: Nobel Biocare,17.

Hough J, Vernon J, Johnson B, Dormer K, Himelick T. (1986a). Experiences with Implantable Hearing Devices and a Presentation of a New Device. *Annals Otol Rhinol Laryngol* 95(1):60-65.

Hough J, McGee M, Himelick T, Vernon J. (1986b). The surgical technique for implantation of the temporal bone stimulator (Audiant TBS). *Amer J Otol* 7(5):315-321.

Hough J, Vernon J, Himelick T, et al (1987). A middle ear implantable hearing device for controlled amplification of sound in the human: a preliminary report. *Laryng* 97:141-151.

Hough JVD, Hough DA, McGee M. (1995). Long-Term Results For The Xomed Audiant Bone Conductor. In: Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryngologic Clinics of North America*, Philadelphia, PA: W.B. Saunders Company, 43-52.

Johnson CE, Danhauer J. (1997). CIC Instruments: Cosmetic Issues. In: M. Chasin (ed). *CIC Handbook*, San Diego, CA: Singular Publishing Group, Inc., (1997).

Kartush JM, Tos M. (1995). Electromagnetic Ossicular Augmentation Device. In: Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryngologic Clinics of North America*, Philadelphia, PA: W.B. Saunders Company, 155-172.

Ko WH, Zhu W-L, Maniglia AJ. (1995). Engineering Principles of Mechanical Stimulation of the Middle Ear. In: Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryngologic Clinics of North America*, Philadelphia, PA: W.B. Saunders Company, 29-42.

Lempert J. (1938). Improvement of hearing in cases of otosclerosis: New one-stage surgical technique. *Arch Otol* 28:42.

Lenkauskas E. (1996). Totally Implantable Hearing Device. In: *2nd International Symposium on Electronic Implants in Otology and Conventional Hearing Aids*, Goteborg, Sweden: Nobel Biocare,19.

Maassen MM, Lehner RR, Buecheler M, Damman F, Zenner HP. (1996). Preoperative assessment of an impantable middle ear pump system using spiral CT scans and conventional X-rays of the temporal bone. In: *2nd International Symposium on Electronic Implants in Otology and Conventional Hearing Aids*, Goteborg, Sweden: Nobel Biocare,23.

Mahoney T, Vernon J. (1974). Speech induced cochlear potentials. *Arch Otolaryngol* 100:403-404.

Maniglia AJ. (1989). Implantable Hearing Devices: State of the art. In: Otology-Current Concepts and Technology, *The Otolaryngologic Clinics of North America*, Phiadelphia, PA: W.B. Saunders Company, 175.

Maniglia AJ. (1996). Personal communication.

Maniglia AJ, Ko WH, Rosenbaum ML, Falk T, Zhu WL, Frenz NW, Werning J, Masin J, Stein A, Sabri A. (1995). Contactless Semi-implantable Electromagnetic Middle Ear Device for the Treatment of Sensorineural Hearing Loss: Short-Term and Long-Term Animal experiments. In: Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryngologic Clinics of North America*, Philadelphia, PA: W.B. Saunders Company, 121-140.

McGee T, Kartush J, Heide J, et al (1991). Electromagnetic semi-implantable hearing device: Phase I clinical trials. *Laryngoscope* 101:355-360.

Mylanus EAM. (1994). The Bone Anchored Hearing aid, Clinical And Audiological Aspects. Dutch: Proefschrift Nijmegen.

Mylanus EAM, Snik AFM, Cremers CWRJ. (1996). Binaural application of the bone anchored hearing aid. In: *2nd International Symposium on Electronic Implants in Otology and Conventional Hearing Aids*, Goteborg, Sweden: Nobel Biocare,36.

Negri S, Bernath O, Hausler R. (1996). Bone conduction implants: Audiant™ vs. BAHA™. In: *2nd International Symposium on Electronic Implants in Otology and Conventional Hearing Aids*, Goteborg, Sweden: Nobel Biocare, 38.

Park JY, Coticchia JM, Clark WW, Esselman GH, Khosla S, Neely JG, Fredrickson JM. (1995). Use of distortion product otoacoustic emissions to assess middle ear transducers in Rhesus Monkeys. *Amer J Otol* 16(5):576-590.

Parkin, JL. (1996). Pedestal design influence on temporal bone osseointegration. In: *2nd International Symposium on Electronic Implants in Otology and Conventional Hearing Aids*, Goteborg, Sweden: Nobel Biocare,14.

Powell RH. (1996). Birmingham Bone Anchored Hearing Programme- Paediatric Experience and Results. In: *2nd International Symposium on Electronic Implants in Otology and Conventional Hearing Aids*, Goteborg, Sweden: Nobel Biocare,44.

Proops DW, Stevenson DS, Hobson JA, Burrell S. (1996). A patient based comparison between the Nobelpharma bone anchored hearing aid and the Xomed Audient [sic] bone conductor. In: *2nd International Symposium on Electronic Implants in Otology and Conventional Hearing Aids*, Goteborg, Sweden: Nobel Biocare,37.

Snik AFM, Mylanus EAM, Cremers CWRJ. (1995). The Bone-Anchored Hearing Aid Compared with Conventional Hearing Aids. In: Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryngologic Clinics of North America*, Philadelphia, PA: W.B. Saunders Company, 73-83.

Spindel JH. (1996). Current status of the Implantable Hearing Aids. Instructional course, American Academy of Audiology, Salt Lake City, Utah.

Spindel JH, Ruth RA, Lambert PR, et al. (1991). Assisted hearing using electromagnetic vibration of an implanted round window magnet. *Ann Biomed Eng* 19:649.

Spindel JH, Lambert PR, Ruth RA. (1995). The Round Window Electromagnetic Implantable Hearing Aid Approach. In: Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryngologic Clinics of North America*, Philadelphia, PA: W.B. Saunders Company, 189-205.

Stevenson SS, Worcester J, Rice RG. (1950). Congenitally malformed infants and associated gestational characteristics. *Paediatrics* 6:37-50.

Suzuki J-I, Yangihara N. (1989). Clinical application of the partial middle ear implant. *Audiology in Practice* 6(1):1-4.

Suzuki J-I, Kodera K, Nagai K, Yabe T. (1994). Long-Term Clinical Results of the Partially Implantable Piezoelectric Middle Ear Implant. *ENT* 73(2): 104-107.

Suzuki J-I, Kodera K, Nagai K, Yabe T. (1995). Partially Implantable Piezoelectric Middle Ear Hearing Device: Long-Term Results. In: Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryngologic Clinics of North America*, Philadelphia, PA: W.B. Saunders Company, 99-106.

Tjellstrom A. (1989). Osseointegrated systems and their applications in the head and neck. *Adv Otolaryngol Head Neck Surg* 3:39-70.

Tjellstrom A, Lindstrom J, Hallen O, et al (1981). Osseointegrated titanium implants in the temporal bone. *Amer J Otol* 2:304-310.

Tjellstrom A, Rosenhall U, Lindstrom J, Hallen O, Branemark P-I. (1983). A five-year experience with skin penetrating bone-anchored implants in the temporal bone. *Acta Otol (Stockh)* 95:568-575.

Tjellstrom A, Jacobsson M, Norvell B, Albrektsson T. (1989). Patients' Attitudes To The Bone-Anchored Hearing Aid. *Scand Audiol* 5:119-123.

Tjellstrom A, Hakansson B. (1995). The Bone-Anchored Hearing Aid: Design Principles, Indications, and Long-Term Clinical Results. In: Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryngologic Clinics of North America*, Philadelphia, PA: W.B. Saunders Company, 53-72.

Tjellstrom A, Granstrom G. (1995). One-stage procedure to establish osseointegration: a zero to five years follow-up report. *J Laryngol Otol* 109:593-598.

Tonndorf J. (1966). Bone conduction. Studies in experimental animals. *Acta Otolaryngol* suppl. 213.

Wade P. (1996). Personal communication.

Wade P, Tollos S, Naiberg J. (1989). Clinical experience with the Xomed Audiant osteointegrated bone conducting hearing device: a preliminary report of seven cases. *J Otol* 18:79-84.

Wade P, Halik J, Chasin M. (1992). Bone Conduction Implants: Transcutaneous vs. percutaneous. *Otolaryng: Head Neck Surg* 106(1):68-74.

Wade P, Chasin M. (1992). Unpublished data on unilateral fittings.

Wade P, Chasin M. (1994). Bone conduction Implants: Transcutaneous vs. percutaneous - 1994. Technical paper presented at the Eastern Section of the Triological Society, Ottawa, Ontario.

Weber B, Roush J. (1991). Implantable Bone-Conduction Hearing Device: Practical Considerations. *J Amer Acad Audiol* 2(2):123-127.

Welling DB, Glasscock ME, Woods C, Sheffey R. (1991). Unilateral sensorineural hearing loss rehabilitation. *Otolaryng-Head Neck Surg* 105(6): 771-776.

Welling DB, Barnes DE. (1995). Acoustic Stimulation of the semicircular canals. In: Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryngologic Clinics of North America*, Philadelphia, PA: W.B. Saunders Company, 207-219.

Yanagihara N, Gyo K, Hinohara Y. (1995). Partially Implantable Hearing Aid Using Piezoelectric Ceramic Ossicular Vibrator: Results of the Implant Operations and Assessment of the Hearing Afforded by the Device. In: Maniglia, A.J. (ed.). Electronic Implantable Devices for Partial Hearing Loss, *The Otolaryngologic Clinics of North America*, Philadelphia, PA: W.B. Saunders Company, 85-98.